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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,527	05/26/2006	Aravinda Thagalingam	16973-2	9351

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Woodard Emhardt
Bank One Center/Tower
111 Monument Circle, Suite 3700
Indianapolis, IN 46204-5137

EXAMINER	
DELLA, JAYMI E	

ART UNIT	PAPER NUMBER
3739	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,527	THAGALINGAM ET AL.	
	Examiner	Art Unit	
	JAYMI DELLA	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-8 and 89-109* is/are pending in the application.

4a) Of the above claim(s) *5,6,108 and 109* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7,8 and 89-107* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/28/2007, 05/05/2006, 05/13/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The following is a non-final, first office action on the merits.

Election/Restrictions

2. Applicant's election of Group I, Set I: Species A, Set III: Species A:, and Set IV: Species A and cancellation of claims 4 and 9-88 in the reply filed on 10/26/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). It is noted in the written restriction that Set II was missing, and thus the claims corresponding to the Set I were in the listing for Set II. However, applicant identified the claims that read on each species. Because only claims readable on **all** elected species that fall within the claims readable for elected Group I are to be examined, claims 1-3, 7-8, and 89-107 are examined below. Claims 5-6 and 108-109 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Objections

5. Claim 7 is objected to because of the following informalities: replace “small diameter disposed with a lumen” with --smaller diameter disposed within a lumen-- in Line 4. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 108-109 recites the limitation "said further lumen" in Lines 2 and 2-3, respectively. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 7-8, 89-92, 94, 97-98, 100-101, 104-105, and 107 are rejected under 35 U.S.C. 102(b) as being anticipated by Laske et al. (7,103,418).

10. Concerning **claim 1**, as illustrated in Fig. 4A and 5, Laske et al. disclose **a surgical device for treating tissue** (70)**, comprising:**

an elongate member with a lumen formed therethrough (72 and 74)**;**

means for manipulating a distal end of the elongate member for placement of said elongate member (Laske et al. disclose that the device 70 be guided by a guide wire through the same path that needle 102 is extended and retracted as a means for deploying the device 70 to the desired site; Column 9, Lines 17-20)**;**

a helical fastening member for fastening the distal end of said elongate member to tissue for screw-in type engagement with said tissue to connect a distal end of said elongate member adjacent to said tissue (76)**;**

means for deploying and retracting said helical fastening member from and into said distal end of said elongate member (conductor 92 and sleeve 80 rotate to deploy and retract the helical member 76 as threaded barrel 86 is actuated on thread guides 90; Columns 9-10, Lines 54-1)**;**

a shaft disposed within said lumen of said elongate member (proximal and distal shaft segments 106 and 104, respectively)**; and**

a needle-like member coupled to said shaft capable of extending from the distal end of said elongate member through said helical fastening member into tissue and being retracted into the end of said elongate member using said shaft, said elongate member, said needle-like member and said helical fastening

member move independently of each other (hollow needle with distal tip 102 extends and retracts through distal end of the elongate member 74 through the helical member 76 into the tissue using shaft 106, and moves independently of the helical member 74; Column 10, Lines 31-34).

11. Concerning **claims 7 and 100**, Laske et al. disclose the elongate member (72, 74) being an outer elongate member; and the deploying and retracting means comprising an inner elongate member of smaller diameter (78) disposed within the lumen of the outer elongate member (72, 74). The helical member (76) is coupled to the distal end of the inner elongate member (78) and rotates about the longitudinal axis of the inner elongate member because when conductor (92) is rotated using a connector pin at its proximal end, this causes rotation of sleeve (80) and advancement of helical electrode (76) as threaded barrel (86) is actuated on thread guides (90). The helical member (76) engages tissue in a screw-in type engagement, and the distal end of the outer elongate member (74) is brought adjacent to the tissue. (Columns 9-10, Lines 54-1 and Column 10, Lines 33-34)

12. Concerning **claim 8**, Laske et al. disclose that when needle tip (102) is extended into the tissue, the distal shaft segment (104) is disposed in the inner elongate member's (78) lumen.

13. Concerning **claim 89**, for purposes of examination, catheter is defined as: "a tubular medical device for insertion into canals, vessels, passageways, or body cavities usually to permit injection or withdrawal of fluids or to keep a passage open" (Merriam Webster Online). Laske et al. disclose elongate member (72, 74) being an elongate

tubular medical device inserted into the body and which permits injection of fluid through hollow needle (102) using fluid delivery device (100).

14. Concerning **claim 90**, Laske et al. disclose the helical member (76) being made of metal (Column 5, Lines 46-47).

15. Concerning **claim 91**, Laske et al. disclose the helical fastening member (76) to be a needle as illustrated in Fig. 5.

16. Concerning **claim 92**, Laske et al. disclose the needle-like member (102) being hollow and capable of delivering a liquid to irrigate the needle like member by injecting fluid through fluid delivery device (100) (Column 10, Lines 24-28).

17. Concerning **claim 94**, Laske et al. disclose the needle-like member being a tip electrode (Column 7, Lines 64-66). It is inherent that the tip electrode is capable of delivering electromagnetic energy to thermally ablate tissue when connected to that source of energy.

18. **Claim 97** is rejected upon the same rationale as presented for claim 89.

19. Concerning **claim 98**, as illustrated in Fig. 4A and 5, the needle-like member (102) is capable of being extended using shaft (106, 104) concentrically, through the helical fastening member (76), since it extends through the middle of the outer elongate member (72, 74) and the helical member.

20. Concerning **claim 101**, Laske et al. disclose a conductor in the form of the needle shaft that extends the length of the outer elongate member (72, 74) that connects the electrode tip to the generator (Column 7, Lines 63-66). It is inherent that the conductor is the needle shaft because Laske et al. disclose insulation isolating

conductor (36) connected to the helical member from the needle tip (Column 8, Lines 45-52). Needle electrode tip (102) is capable of delivering electromagnetic energy for thermal ablation when connected with that source of energy.

21. Concerning **claims 104-105**, for purposes of examination, valve is defined as: "any device for halting or controlling the flow of a liquid, gas, or other material through a passage, pipe, inlet, outlet, etc." (www.dictionary.com). Laske et al. disclose seal (82) molded to the distal end of the inner elongate sleeve (78) and extending between the inner elongate member (78) and the needle-like member (106). Sealing ring (84) is located between the inner elongate member (78) and outer elongate member (72, 74). Together, they complete a fluid-tight seal to prevent the ingress of body fluids. (Column 10, Lines 12-23; Fig. 5)

22. Concerning **claim 107**, for purposes of examination, adjacent is defined as: "lying near, close, or contiguous" (www.dictionary.com). Laske et al. disclose the needle-like member (102) having an outlet at its distal tip, and thus contiguous with its distal tip, to dispense fluid, and is thus capable of dispensing irrigation fluid (Column 10, Lines 24-28).

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

24. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

25. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

26. Claims 2-3 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laske et al. (7,103,418), as applied to claim 1, in further view of Bens (5,259,394).

27. Concerning **claims 2-3 and 99**, Laske et al. fail to disclose the deploying and retracting means comprising a shape memory alloy wire and where the helical fastening member is part of the shape memory alloy wire. However, Bens discloses an endocardial lead with a helical fastening element (6) that is made of a shape memory

alloy wire such as nitinol, that when extended out of the end of the electrode (3) on the proximal end of the sheath (1) the helix (6) deploys to a substantially larger diameter than the inner diameter of the electrode (3) and the sheath (1). Further, when the helix (6) is retracted, it reverts to its previous smaller diameter form. At the time of the invention, it would have been obvious to one of ordinary skill in the art to have a shape memory alloy helical fastening member as a means for deploying and retracting the helix in order to provide the benefit of making producing a helix having a greater extended outer diameter than a retracted inner diameter as taught by Bens. (Column 6, Lines 1-25; Fig. 1-2)

28. Claims 93 and 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laske et al. (7,103,418), as applied to claim 1, in further view of Osypka (5,964,754, cited in IDS).

29. Concerning **claim 93**, Laske et al. disclose monitoring electrophysiological signals (Column 8, Lines 58-61), but fail to disclose a plurality of temperature sensing or measuring devices attached to the needle-like member and arranged at intervals to enable sensing or monitoring of temperature at a plurality of tissue depths. Osypka discloses a catheter with an extendable hollow coagulation needle (6) that can inject medication. Inside the needle (6), is a temperature sensor (9) that indicates and/or controls the high frequency generator (5). At the time of the invention, it would have been obvious to one of ordinary skill in the art to use a temperature sensor in the hollow needle in order to provide the benefit of regulating the high frequency generator so that

the coagulation process and especially the temperature in connection with it arising in the tissue adjacent the needle where the sensors are located can be monitored and, if necessary, be automatically controlled or regulated to avoid too low or too high temperatures as taught by Osypka. (Column 6, Lines 52-65; Fig. 1 and 7) Further, it would have been obvious to one of ordinary skill in the art It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a plurality of temperature sensors in order to provide the benefit of sensing temperature at different locations of tissue adjacent the needle to avoid too low or too high temperatures as taught by Osypka, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

30. Concerning **claim 103**, Laske et al. fail to disclose an ultrasound sensing device located within the needle-like member. However, Osypka discloses an ultrasound sensing device located within the needle-like member (6) that provides the benefit of measuring the thickness of the heart wall (2) and penetration depth of the needle (6) (Columns 6-7, Lines 66-4; Fig. 7). At the time of the invention, it would have been obvious to one of ordinary skill in the art to include an ultrasound sensor in the needle in order to provide the benefit of measuring the thickness of the heart wall and penetration depth of the needle a taught by Osypka.

31. Claims 95-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laske et al. (7,103,418), as applied to claim 94, in further view of Daly et al. (2001/0020166).

32. Concerning **claims 95-96**, Laske et al. teach using an electrode needle as discussed in the rationale for claim 94, but fail to explicitly disclose a means for measuring the temperature of at least a portion of the needle and ring electrodes attached to the exterior of the needle-like member for measuring electrical activity from and pacing nearby tissue. However, Daly et al. disclose a system (2,4) for ablating tissue using a needle probe (20) that has multiple ring electrodes (22A-22D) through which RF energy is delivered. Each electrode has a corresponding thermocouple/temperature sensor (36A-36D) that measures the temperature of the electrode. These temperatures are used to control each electrode independently in order to advantageously regulate temperatures that occur at each electrode to produce an optimum lesion size and avoid charring and vaporization associated with temperatures greater than one hundred degrees Celsius since the lesion size is proportional to the temperature. Further, because of the ability to maintain all electrodes at a desired temperature simultaneously and independently, enables contiguous uniform lesions. ([0071], Lines 1-5; [0074], Lines 4-6; [0075], Lines 5-9); [0076], Lines 1-6 and 11-16) At the time of the invention, it would have been obvious to one of ordinary skill in the art to use a probe with multiple ring electrodes, each being individually controlled and having its own temperature sensor, in order to provide the benefit of producing an optimum and uniform lesion size and avoiding charring and

vaporization at too high of a temperature as taught by Daly et al. It naturally flows that these ring electrodes are capable of measuring electrical activity from and pacing nearby tissue when the correct electromagnetic signal is applied.

33. Claim 102 is rejected under 35 U.S.C. 103(a) as being unpatentable over Laske et al. (7,103,418), as applied to claim 1, in further view of Galt et al. (6,425,854).

34. Concerning **claim 102**, Laske et al. disclose the needle-like member (102) having an outlet at its distal tip to dispense fluid, and is thus capable of dispensing irrigation fluid (Column 10, Lines 24-28). Laske et al. fail to disclose an irrigation tube within the needle-like member. However, Galt et al. disclose a needle (110', 112') having a lumen within which is an inner cannula (116'), taken to be the irrigation tube, through which fluid is dispensed (Column 6, Lines 31-47; Fig. 16). At the time of the invention, it would have been obvious to one of ordinary skill in the art to include an irrigation tube in order to provide the benefit of keeping the fluid from contacting the electrically conductive shaft to avoiding ionizing the fluid.

35. Claim 106 is rejected under 35 U.S.C. 103(a) as being unpatentable over Laske et al. (7,103,418), as applied to claim 1, in further view of Altman et al. (6,547,787).

36. Concerning **claim 106**, Laske et al. fail to disclose the manipulating means comprising a pull wire connected to a metal ring attached to the distal portion of the

outer elongate member. However, Altman et al. disclose a steerable catheter with a helical fixation member and needle-like member extending through the helical member (Fig. 1a). The catheter is guided by one or more pull wires connected to a steering knob (2304), which is connected to wheel, or ring (2308), attached to the distal which effects deflection of the distal end of the steerable catheter (Column 29, Lines 9-12; Fig. 23), where ring is defined as: "the outside edge of a circular body, as a wheel" (www.dictionary.com). At the time of the invention, it would have been obvious to one of ordinary art to use a manipulating means comprised of a pull wire and steering ring in order to provide the benefit of deflecting to the distal end of the catheter to the target location without having to first insert a guidewire as taught by Altman et al. Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the ring of metal, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. See also *Ballas Liquidating Co. v. Allied industries of Kansas, Inc.* (DC Kans) 205 USPQ 331.

Conclusion

37. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Altman et al. (6,358,247, cited in IDS), Altman et al. (6,296,630), and Rosenman et al. (6,478,776), and Vachon (5,531,780, cited in IDS) all disclose

surgical devices comprising helical fastening members and needles extending concentrically through the helical fastening members.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAYMI DELLA whose telephone number is (571)270-1429. The examiner can normally be reached on M-Th 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571)272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Linda C Dvorak/
Supervisory Patent Examiner, Art Unit 3739

/J. D./
Examiner, Art Unit 3739
November 30, 2009